K024309

Advanced Respiratory

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FEB 21 2003

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SUMMARY OF SAFETY AND EFFECTIVENESS
This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990.

Submitter: Eric J. Larson
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Contact person: Eric J. Larson

Name of Device: Modified Vest™ Airway Clearance System

Classification: Powered Percussor, Class II

Predicate Device: The Vest™ Vest System, 510(K) number: **K012928, K993629**

Description of Device:
The Advanced Respiratory Vest™ Airway Clearance System is a high-frequency chest wall oscillator designed to be used in a wide variety of settings for enhancing the mobilization of bronchial secretions. The primary components of The Vest™ Airway Clearance System include an air-pulse generator and an inflatable vest. Oscillating positive pressure air pulses are applied to the vest by the air-pulse generator. The resulting pressure pulses cause the vest to inflate and deflate against the chest of the user creating high-frequency chest wall oscillation and mobilization of bronchial secretions.

SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

Intended Use:
The intended use of the Advanced Respiratory Vest Airway Clearance System is to promote airway clearance or improve bronchial drainage by enhancing mobilization of bronchial secretions where external manipulation of the thorax is the physician's choice of treatment. The indications typically follow the Clinical Practice Guideline published by the American Association for Respiratory Care (AARC) 1991. In addition, the device is also indicated for the purpose of collecting mucus for diagnostic evaluation.

Comparison of Technological Characteristics:
The Modified Vest™ System is equivalent to Advanced Respiratory's previously cleared LINK Vest™ Airway Clearance System (K012928) and its Vest™ Airway Clearance System (a.k.a. ThAIRapy® Vest System) (K993629) in that the new model is intended to promote airway clearance or improve bronchial drainage by enhancing the mobilization of bronchial secretions when external manipulation of the thorax is the physician's choice of treatment. All devices have reciprocating bellows that generate the air pulses. The same vests will be used on the new device as were available for the predicate devices. Operator controls remain consistent with predicate devices. The user can adjust air pulse frequency and pressure. The reason for this submission is to due to the change from analog to digital control of device frequency and pressure. The predicate device contains analog potentiometers that were rotated to control device frequency and pressure. The new device has momentary switches that are depressed to send a digital signal for microprocessor control of frequency and pressure.

Performance Testing:

The Modified Advanced Respiratory Vest™ Airway Clearance System was compared to the predicate model The Vest™ ThAIRapy System (K993629). Functional and performance comparisons were made and it is concluded that the device that is the subject of this 510(k) is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2003

Advanced Respiratory
C/O Mr. Ned E. Devine
Entela, Incorporated
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K024309
Trade/Device Name: The Vest™ Airway Clearance System
Regulation Number: 868.5665
Regulation Name: Powered Percussor
Regulatory Class: II
Product Code: BYI
Dated: February 6, 2003
Received: February 7, 2003

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number (if known) K024309

Device Name: Modified Vest™ Airway Clearance System

Indications for use:

The intended use of the Modified Vest™ Airway Clearance System is the same as the predicate device, which is to provide airway clearance therapy when external manipulation of the thorax is the physician's choice of treatment. Indications for this form of therapy are described by the American Association for Respiratory Care (AARC) in the Clinical Practices Guidelines for Postural Drainage Therapy[1] (1991). According to AARC guidelines, specific indications for external manipulation of the thorax include evidence or a suggestion of retained secretions, evidence that the patient is having difficulty with the secretion clearance, or presence of atelectasis caused by mucus plugging. In addition, the Vest™ Airway Clearance System is also indicated for external manipulation of the thorax to promote airway clearance or improve bronchial drainage for purposes of collecting mucus for diagnostic evaluation.

1. Bronchial Hygiene Guidelines Committee, American Association for Respiratory Care. AARC clinical practice guideline: postural drainage therapy. Respiratory Care 1991; 36: 1418 – 1426.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K024309